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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,238	10/12/2001	David A. Basiji	BIOL0029	9708

25268 7590 09/09/2004

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,238

Applicant(s)

BASIJ ET AL.

Examiner

MY-CHAU T TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-12 and 41-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8-12 and 41-52 is/are rejected.
- 7) ☒ Claim(s) 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/23/2004 has been entered.

Petition

2. The petition under 37 CFR 1.137(b), filed 4/23/2004, is granted and mailed 6/22/2004.

Status of Claims

3. Applicant's amendment filed 2/9/2004 is acknowledged and entered. Claims 1-2, and 8 have been amended. Claims 49-52 have been added.

4. Claims 3-7, and 13-40 were canceled, Claims 1 and 8 were amended, and Claims 41-48 were added by the amendment filed on 7/11/2003.

5. Claims 1-2, 8-12, and 41-52 are pending.

6. This application claims priority to two provisional applications. They are 60/242,734, filed 10/23/2000, and 60/240,125 filed 10/12/2000.

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7. Claims 1-2, 8-12, and 41-52 are treated on the merit in this Office Action.

Claim Objections

8. Claim 49 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-2, and 41-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claim 1 recites a method of constructing a blank library of optically distinct reporter labeled carriers. The method comprises the steps of: (a) providing a plurality of carriers, at least some of which are identical, each carrier being configured to support a plurality of optically distinct reporters and a plurality of compounds of interest, none of the plurality of

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carriers as initially provided having any reporters or compounds of interest attached thereto; (b) providing a plurality of reaction vessels, such that at least one reaction vessel is available for each unique member of the blank library to be constructed; (c) providing a plurality of optically distinct reporters, such that at least some of the plurality of optically distinct reporters are different from each other; (d) in each reaction vessel, apportioning at least one carrier, such that any reaction vessel that includes more than one carrier will include only identical carriers; (e) in each reaction vessel, apportioning at least one optically distinct reporter, such that a unique combination of the at least one carrier and the at least one optically distinct reporter is achieved in each reaction vessel, and such that the optically distinct reporters in each vessel enable each carrier in that vessel to be distinguished from carrier and reporter combinations in other vessels; (f) attaching said at least one optically distinct reporter to said at least one carrier in each reaction vessel, such that each carrier in the same reaction vessel will have an identical set of optically distinct reporters attached to it, each reaction vessel including a set of optically distinct reporter labeled carriers that is uniquely different from the optically distinct reporter labeled carriers of each other reaction vessel, the plurality of reaction vessels thereby defining a blank library of optically distinct reporter labeled carriers such that compounds of interest can later be attached to the optically distinct reporter labeled carriers of the blank library.

The claimed method of constructing a blank library of optically distinct reporter labeled carriers of claim 1, have no clear support in the specification and the claims as originally filed. The specification in page 12 disclosed '*a method for the production of a reporter-labeled carrier library by the addition of all required reporter system in a single step prior to the synthesis or addition of the chemical compounds to the carrier*' (lines 10-30; fig. 8-9) is not support for the

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claimed method of constructing a blank library of optically distinct reporter labeled carriers. Because the specification recites the method of making a library of reporter-labeled carrier wherein the resulting library *include* attached chemical compounds, it does not support the claimed method of constructing a blank library of optically distinct reporter labeled carriers wherein the resulting library *does not include* attached chemical compounds. Furthermore, the specification disclosure is silent on the claimed method steps for producing a blank library of optically distinct reporter labeled carriers. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of the claimed method of constructing a blank library of optically distinct reporter labeled carriers wherein the resulting library *does not include* attached chemical compounds.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

11. Claims 8-12, and 45-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claim 8 recites method of constructing a blank library of optically distinct reporter labeled carriers. The method comprises the steps of: (a) providing a plurality of optically distinct carriers at least some of which are identical, each carrier being configured to support a plurality of optically distinct reporters and a plurality of compounds of interest none of

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the plurality of carriers as initially provided having any reporters or compounds of interest attached thereto; (b) providing a plurality of reaction vessels, such that at least one reaction vessel is available for each unique member of the library to be constructed; (c) providing a plurality of optically distinct reporters, such that at least some of the plurality of optically distinct reporters are different from each other; (d) in each reaction vessel, apportioning at least one optically distinct carrier and at least one optically distinct reporter, such that: (i) any one of the plurality of reaction vessels that includes more than one optically distinct carrier will include only identical optically distinct carriers; and (ii) a unique combination of the at least one optically distinct carrier and the at least one optically distinct reporter is achieved in each reaction vessel; and (e) attaching said at least one reporter to said at least one carrier in each reaction vessel, such that each optically distinct carrier in the same reaction vessel will have an identical set of optically distinct reporters attached to it, each reaction vessel including a set of optically distinct reporter labeled carriers that is uniquely different from the optically distinct reporter labeled carriers of each other reaction vessel, the plurality of reaction vessels thereby defining a blank library of optically distinct reporter labeled carriers such that compounds of interest can later be attached to the optically distinct reporter labeled carriers of the blank library.

The claimed method of constructing a blank library of optically distinct reporter labeled carriers of claim 8, have no clear support in the specification and the claims as originally filed. The specification in page 12 disclosed '*a method for the production of a reporter-labeled carrier library by the addition of all required reporter system in a single step prior to the synthesis or addition of the chemical compounds to the carrier*' (lines 10-30; fig. 8-9) is not support for the claimed method of constructing a blank library of optically distinct reporter labeled carriers.

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Because the specification recites the method of making a library of reporter-labeled carrier wherein the resulting library *include* attached chemical compounds, it does not support the claimed method of constructing a blank library of optically distinct reporter labeled carriers wherein the resulting library *does not include* attached chemical compounds. Furthermore, the specification disclosure is silent on the claimed method steps for producing a blank library of optically distinct reporter labeled carriers. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of the claimed method of constructing a blank library of optically distinct reporter labeled carriers wherein the resulting library *does not include* attached chemical compounds.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

12. Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claim 49 recites a method of constructing a library of optically distinct reporter labeled carriers to which no compounds of interest are yet attached. The method comprises the steps of: (a) providing a plurality of carriers, at least some of which are identical, each carrier being configured to support a plurality of optically distinct reporters and a plurality of compounds of interest, none of the plurality of carriers as initially provided having any

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reporters or compounds of interest attached thereto; (b) providing a plurality of reaction vessels, such that at least one reaction vessel is available for each unique member of the blank library to be constructed; (c) providing a plurality of optically distinct reporters, such that at least some of the plurality of optically distinct reporters are different from each other; (d) in each reaction vessel, apportioning at least one carrier, such that any reaction vessel that includes more than one carrier will include only identical carriers; (e) in each reaction vessel, apportioning at least one optically distinct reporter, such that a unique combination of the at least one carrier and the at least one optically distinct reporter is achieved in each reaction vessel, and such that the optically distinct reporters in each vessel enable each carrier in that vessel to be distinguished from carrier and reporter combinations in other vessels; (f) attaching said at least one optically distinct reporter to said at least one carrier in each reaction vessel, such that each carrier in the same reaction vessel will have an identical set of optically distinct reporters attached to it, each reaction vessel including a set of optically distinct reporter labeled carriers that is uniquely different from the optically distinct reporter labeled carriers of each other reaction vessel, the plurality of reaction vessels thereby defining a blank library of optically distinct reporter labeled carriers such that compounds of interest can later be attached to the optically distinct reporter labeled carriers of the blank library.

The claimed method of constructing a library of optically distinct reporter labeled carriers to which no compounds of interest are yet attached of claim 49, have no clear support in the specification and the claims as originally filed. The specification in page 12 disclosed *'a method for the production of a reporter-labeled carrier library by the addition of all required reporter system in a single step prior to the synthesis or addition of the chemical compounds to the*

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carrier' (lines 10-30; fig. 8-9) is not support for the claimed method of constructing a blank library of optically distinct reporter labeled carriers. Because the specification recites the method of making a library of reporter-labeled carrier wherein the resulting library *include* attached chemical compounds, it does not support the claimed method of constructing a library of optically distinct reporter labeled carriers to which no compounds of interest are yet attached. Furthermore, the specification disclosure is silent on the claimed method steps for producing a blank library of optically distinct reporter labeled carriers. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of the claimed method of constructing a library of optically distinct reporter labeled carriers to which no compounds of interest are yet attached.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

13. Claims 50-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claim 50 recites a method of constructing a blank library of optically distinct reporter labeled carriers. The method comprises the steps of: (a) providing a plurality of optically distinct reporters, such that at least some of the plurality of optically distinct reporters are different from each other; (b) based on the number of different optically distinct reporters

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provided, determining all possible binary codes that can be produced using the optically distinct reporters provided; (c) providing a plurality of reaction vessels, such that each reaction vessel corresponds to a specific binary code; (d) providing a plurality of carriers, at least some of which are identical, each carrier being configured to support a plurality of optically distinct reporters and a plurality of compounds of interest, none of the plurality of carriers as initially provided having any reporters or compounds of interest attached thereto; (e) in each reaction vessel, apportioning the optically distinct reporters required to produce the binary code corresponding to the reaction vessel; (f) in each reaction vessel, apportioning at least one carrier, such that any reaction vessel that includes more than one carrier will include only identical carriers; and (g) in each reaction vessel, attaching the optically distinct reporters defining the binary code for the reaction vessel to each carrier in the reaction vessel, such that each carrier in the same reaction vessel will have an identical set of optically distinct reporters attached to it, each reaction vessel including a set of optically distinct reporter labeled carriers that is uniquely different from the optically distinct reporter labeled carriers of each other reaction vessel, the plurality of reaction vessels thereby defining a blank library of optically distinct reporter labeled carriers, such that compounds of interest can be later attached to the optically distinct reporter labeled carriers of the blank library.

The claimed method of constructing a blank library of optically distinct reporter labeled carriers of claim 50, have no clear support in the specification and the claims as originally filed. The specification in page 12 disclosed '*a method for the production of a reporter-labeled carrier library by the addition of all required reporter system in a single step prior to the synthesis or addition of the chemical compounds to the carrier*' (lines 10-30; fig. 8-9) is not support for the

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claimed method of constructing a blank library of optically distinct reporter labeled carriers. Because the specification recites the method of making a library of reporter-labeled carrier wherein the resulting library **include** attached chemical compounds, it does not support the claimed method of constructing a blank library of optically distinct reporter labeled carriers wherein the resulting library **does not include** attached chemical compounds. Furthermore, the specification disclosure is silent on the claimed method steps for producing a blank library of optically distinct reporter labeled carriers. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of the claimed method of constructing a blank library of optically distinct reporter labeled carriers wherein the resulting library **does not include** attached chemical compounds.

The recitation of step “(b) based on the number of different optically distinct reporters provided, determining all possible binary codes that can be produced using the optically distinct reporters provided” claimed in claim 50, have no clear support in the specification and the claims as originally filed. The specification in page 14 disclosed ‘one method of combining four color species of singly-labeled microbeads to produce all possible binary color codes in 2^4 reaction vessels’ (lines 31-33; fig. 14) is not support for the step ‘(b) based on the number of different optically distinct reporters provided, determining all possible binary codes that can be produced using the optically distinct reporters provided’. Because the narrow limitation of the specification recites using four different color species and calculating the possible combination of different color species that can derive on one microbeads, it does not support the broad limitation of the claim, which recites **any** type of reporters wherein the claimed reporter would encompasses a broad genus of reporter, e.g. fluorescent label, amino acid, or dendrimer, and

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determining the binary codes. Furthermore, the claimed method step (b) is interpreted as a thought process, which is not a patentable subject matter. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of step '*(b) based on the number of different optically distinct reporters provided, determining all possible binary codes that can be produced using the optically distinct reporters provided*'.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-2, 8-12, and 41-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "at least some" of claims 1, 8, 49, and 50 is vague and indefinite because it is unclear what constitutes the metes and bounds of "some", i.e. what is the lower limit. Is it 2? 10? 100? Thus the phrase "at least some" of claims 1, 8, 49, and 50 are vague and indefinite.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-2, 8-12, and 41-49 are rejected under 35 U.S.C. 102(b) as being anticipated by The University of Queensland (WO 99/24458).

WO 99/24458 teaches the method of using an assembly of carrier having one or more reporter beads that are non-covalently attached in a combinatorial split-process-recombine procedure (see e.g. Abstract; pg. 1, lines 4-7; pg. 6, lines 21-24; pg. 7, lines 2-4; figs. 6-8). The method comprises the steps of 1) the carriers are split into two portions in reaction vessels; 2) one portion is mixed with the red reporter beads and the other portion is mixed with the green reporter beads (refers to claims 1-2, 8-9, and 49); 3) the carrier is wash to remove excess reporter beads; 4) different monomers are added to each portion mixture; 5) the portion mixtures are recombine and split into two portions; and steps 2-5 are repeated until a library of molecules is formed wherein each molecules will have a unique signal associated with it (see pg. 7, line 13 to pg. 8, line 7; pg. 32, line 12 to pg. 34, line 10; figs. 6-8). The reporter beads have properties such as color, fluorescence signal, and detectable physical feature such as size wherein the sequence of the synthesis applied to any carrier is determine from the reporter bead attached to the carrier (refers to claims 10-11, 41-48) (see pg. 24, lines 7-20; figs. 6-8). Therefore, the method of WO 99/24458 anticipates the presently claimed method.

18. Claims 1-2, 8-12, and 41-52 rejected under 35 U.S.C. 102(e) as being anticipated by Seul et al. (US Patent Application Publication 2002/0090613 A1; *filing date 11/22/1999*).

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Seul et al. teaches a method for the physio-chemical encoding (refers to reporters) of a collection of beaded resin to determine the chemical identity of bead-anchored compounds (see e.g. Abstract; paragraphs: [002], [0026], and [0085]-[0102]). The encoding of the beads is a set of fluorophores that provide binary and extended binary codes (refers to claims 11, 43-44, 47-48, and 52) (see e.g. paragraphs: [0027], and [0042]-[0054]) and the color codes is further augmented by varying the parameters of the beads such as shape, and size (refers to claims 10, 12, 41-42, and 45-46) (see e.g. paragraphs: [0029], and [0056]). The method comprises the steps of providing plurality reaction vessels wherein each reaction vessel contains plurality of beads, adding to each vessel a different fluorophores that would result in different color encoded beads for each reaction vessels (refers to claims 1-2, 8-9, 49, and 50-51) (see e.g. paragraphs: [0085]-[0102], and [0106]-[0107]). Thus the method of Seul et al. anticipates the presently claimed method.

19. Claims 1-2, 8-9, 11, 43-44, and 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by The University of Queensland (WO 00/32542; *filing date 11/30/1998*).

WO 00/32542 teaches a method of producing plurality of carriers that are pre-encoded with information sufficient to distinguish it from a heterogeneous population of carriers (see e.g. Abstract; pg. 1, lines 3-7; pg. 7, lines 11-23; pg. 19, lines 1-9; pg. 27, lines 7-17; pg. 43, lines 1-11). The method comprises the steps of providing separate batches of seed microspheres with different concentration of fluorophores for each batch, repooling and randomly splitting into new batches, and adding different concentrations of new fluorophore to each batch (refers to claims 1-

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2, 8-9, and 49) (see e.g. pg. 7, lines 11-23; pg. 19, lines 1-9; pg. 27, lines 7-17; pg. 43, lines 1-11). Thus the method of WO 00/32542 anticipates the presently claimed method.

Withdrawn Rejections

20. The rejection of claims 1-2, 41-44 under 35 USC 102(b) as being anticipated by Wang et al. (US Patent 5,922,617) has been withdrawn in light of applicant's amendments of claim 1.

21. The rejection of claims 1-2, 8-12, 43-44, and 47-48 under 35 USC 102(b) as being anticipated by Still et al. (US Patent 5,565,324) has been withdrawn in light of applicant's amendments of claims 1 and 8.

22. The rejection of claims 8-12, and 45-48 under 35 USC 103(a) as being obvious over Wang et al. (US Patent 5,922,617) in view of Furka (WO 93/24517) has been withdrawn in view of applicant's amendments of claim 8.

Response to Arguments

23. Applicant's arguments with respect to claims 1-2, 8-12, and 41-48 have been considered but are moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810.

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The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
September 7, 2004


PADMASHRI PONNALURI
PRIMARY EXAMINER